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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,204	06/06/2001	Gordon C. Shore	50013/011002	2246

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/30/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/876,204

Applicant(s)

SHORE ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,10,14,15 and 30-42 is/are pending in the application.
- 4a) Of the above claim(s) 33,34,40 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,10,14,15,30-32,35-39 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 5/19/2003 (paper no. 6) is acknowledged and entered into the record. Accordingly, claims 3-5, 7-9, 11-13, and 16-29 are canceled without prejudice or disclaimer and claims 30-42 are newly added.
2. Claims 1-2, 6, 10, 14-15, and 30-42 are pending, claims 33, 34, 40 and 41 are withdrawn from further consideration as being drawn to non-elected species.
3. Therefore, claims 1-2, 6, 10, 14-15, and 30-32, 35-39, and 42 are examined on the record.

Claim Rejections Withdrawn - 35 USC § 112, 2nd paragraph

4. The rejection of claims 1 and 10 under 35 USC 112, 2nd paragraph is withdrawn in view of the amendments to the claims.
5. The rejection of claims 3, 4 and 12 are rendered moot in view of the claim cancellations.

Claim Rejections Withdrawn - 35 USC § 112, 1st paragraph

6. The rejection of claims 3-5 and 11-13 are rendered moot in view of the cancellation of the claims.

Claim Rejections Maintained - 35 USC § 102

7. The rejection of claims 1-2, 6, 10, 14-15 and now newly added claim 35, under 35 USC 102(e) is maintained for the reasons of record. Applicant argues that the claims

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are drawn to a protein that consists essentially of or consists of the BAX ART domain which is defined as the N-terminal portion of BAX (14 amino acids in length) which has a general motif of SEQ ID No: 1. Applicant further argues that the Korsmeyer *et al* patent teaches full length BAX and not BAX ART domain. Applicant's arguments have been carefully considered but are not considered persuasive. Applicant's use of the term "consisting essentially of" renders the claim to open interpretation and would thus fall within the scope of the full length BAX protein disclosed by Korsmeyer *et al* (SEQ ID No: 2) because the full-length BAX of Korsmeyer *et al* comprises or consists essentially of SEQ ID No: 1 or SEQ ID No: 3.

NEW ARGUMENTS

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-2,6, and 30-32, 35-36 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-2,6, and 30-36, as written, do not sufficiently distinguish over proteins as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the

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inventor, e.g., by insertion of "Isolated" or "Purified" as taught by page 8 of specification.

See MPEP 2105.

Claim Rejections - 35 USC § 112

10. Claims 10,14-15,37-39, and 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising SEQ ID No: 1 or 3 or a composition comprising SEQ ID No: 1 or 3 for in vitro usage, does not reasonably provide enablement for a pharmaceutical composition comprising SEQ ID No: 1 or 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are drawn to a pharmaceutical composition consisting essentially of SEQ ID No: 1 or 3 and a pharmaceutical carrier. The claims are also drawn to pharmaceutical compositions that consists of SEQ ID No: 1 or 3 and a pharmaceutical carrier. The art teaches that the delivery of anti-cancer drugs to patients often meets with some difficult barriers and circumstances. Jain (Sci Am. 1994 Jul;271(1):58-65) teaches that although effective in culture, the translation of anti-cancer drugs into in vivo settings is often met with some challenges such as the ability of a drug to penetrate into the tough barrier of a solid tumor. Furthermore, Dermer (Bio/Technology 1994;12:320) teaches that the discovery of drugs that are effective on cultured cell lines are not indicative of the cells in vivo because of the "evolutionary-type step" a cell line takes in vitro.

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The specification teaches that BAX ART, the N-terminal portion of the BAX protein is required for the proper insertion of BAX into the mitochondrial membrane. In the absence of a death signal, the BAX ART domain is associated with the BAX transmembrane domain (TM) thereby preventing its initiation of apoptosis. However, upon the transduction of a death signal, BAX transmembrane domain is released from the ART domain thereby allowing insertion into the mitochondrial membrane. The specification teaches this by constructing BAX protein missing the ART domain. The specification thereby concludes that if a BAX ART domain was administered, it would be associated with the TM domain even in the presence of a death signal thereby preventing apoptosis. However, the specification has not taught the full scope of the claims because the administration of peptides is not as predicative or easy as one would believe. The specification has not taught how the peptide would be administered, the bioavailability of the peptide at the site of interest, how the peptide is to translocate into the cell, the immune responses generated from the administration of the peptide. Because the art of peptide administration is not predictive nor clearly taught in the specification, one of skill in the art is essentially forced to determine multiple factors in order to practice the invention. Although it is noted that the claims are drawn to the product per se, the requirements of 35 USC 112, 1st paragraph must allow one of skill in the art to practice the invention without having to perform undue experimentation. Because of the unpredictability of peptide administration and the effectiveness of peptide drugs testing in vitro, as evidenced by Jain and Dermer *et al*, the skilled artisan is essentially forced into experimentation to use the instant invention.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-2, 6, 10, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Apte SS *et al* (Genomics 1995 Apr;26(3):592-594). The claims are drawn to a polypeptide consisting essentially or has a BAX ART domain wherein the BAX ART domain is represented by the motif of SEQ ID No: 1 and/or has the sequence of SEQ ID No: 3. Apte SS *et al* teaches a protein that consists essentially of SEQ ID No: 3 and falls within the motif represented by SEQ ID No: 1.

13. Claims 1-2, 6, 10, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Oltvai *et al* (Cell 1993 Aug;74(4):609-19). The claims are drawn to a polypeptide consisting essentially or has a BAX ART domain wherein the BAX ART domain is represented by the motif of SEQ ID No: 1 and/or has the sequence of SEQ ID No: 3. Apte SS *et al* teaches a protein that consists essentially of SEQ ID No: 3 and falls within the motif represented by SEQ ID No: 1.

Conclusion

14. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Christopher Yaen
Art Unit 1642
July 22, 2003



ANTHONY C. CAPUTO
SUPERVISORY PATENT EXAMINER
TECHNICAL FIELD: 1642